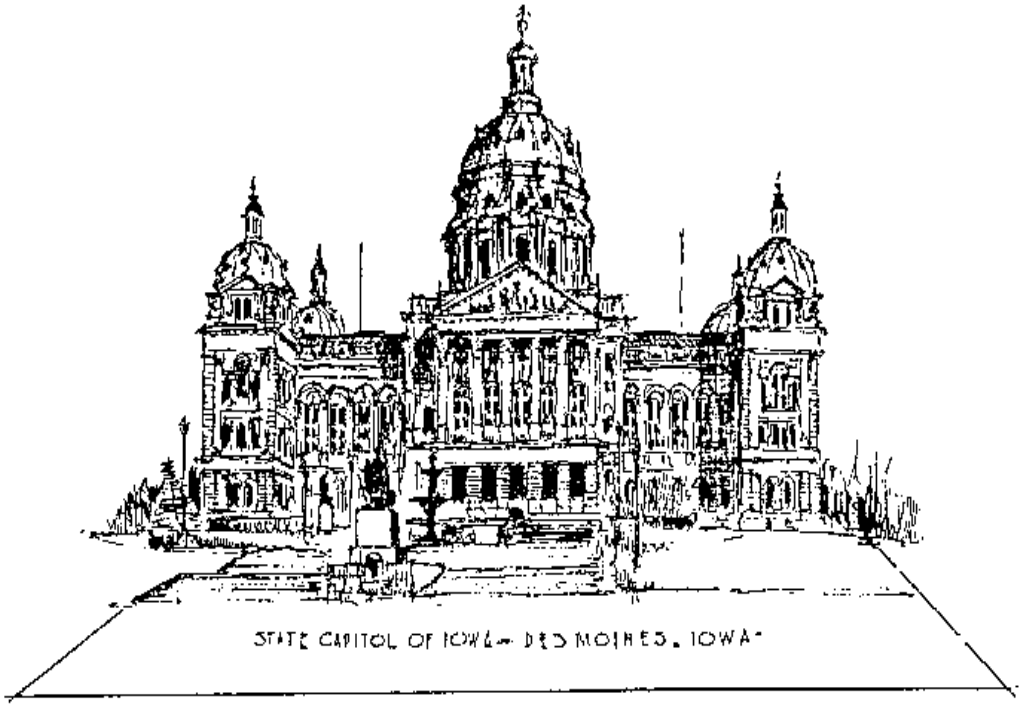
IOWA DEPARTMENT OF PUBLIC HEALTH

BROADSCOPE LICENSE REGULATORY GUIDE



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REGULATORY GUIDE FOR BROADSCOPE LICENSES

1. INTRODUCTION

1.1 -- GENERAL

This guide outlines the type and extent of information needed by the Iowa Department of Public Health (IDPH) staff to evaluate applications for a specific license of broadscope for byproduct material. The IDPH regulations in 641 Chapter 39 provides for three distinct categories of licenses for broadscope (i.e., Type A, Type B and Type C) licenses. 641-39.4(28)"a" defines these type licenses. This guide is intended to outline the information to be provided in the preparation and review of applications for Type A and B licenses, which authorize use of licensed materials in a variety of fields and occupations. Such licenses may include:

- manufacturing and distribution of licensed materials in calibration and/or test sources;
- measuring devices;
- universities limited to academic research and development;
- medical institutions involved in human research;
- both medical and non-medical applications; or
- a combination of the above areas

Broadscope licenses authorize possession of a variety of radioactive material without each radionuclide and authorization specifically listed on the license. The guidance outlined in this Regulatory Guide (Broadscope Regulatory Guide) presents a philosophical approach that should aid in the development of a radiation safety program. It should also aid in the preparation of an application that is acceptable to the IDPH staff. Your application for a broadscope license can also include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding).

1.2 -- CONCEPT AND CONDITIONS OF BROADSCOPE LICENSES

Broadscope licenses will be issued only to organizations that have:

1. Considerable prior experience in the use of radioactive materials under limited scope specific licenses. Although not specified in the regulations, it is recommended that an applicant have had a limited specific license for at least a 5-year period.
2. A good regulatory performance record, based on IDPH licensing and inspection of prior activities.
3. A radioactive materials utilization program of such scope that the organization requires a variety of radionuclides and the operational flexibility to cover numerous uses and users.
4. An administrative structure, organization and procedures adequate to ensure safe operations and to review and approve proposed uses, users, facilities, and procedures incorporated into the license.

A broadscope license is intended to accommodate those organizations involved in an extensive radioactive material program where the demand is great for a variety of radionuclides and uses. Type A and B licenses are the most comprehensive issued and may be written to cover a wide range of radionuclides (e.g., all radionuclides with atomic numbers 1 through 83). The use of byproduct materials authorized by a Type A license is required to be controlled by a Radiation Safety Committee and qualified Radiation Safety Officer and staff. An individual, i.e., a Radiation Safety Officer, controls a Type B license.

Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the Radiation Safety Officer and the range of intended uses. Type B licenses are not as diverse as a Type A license.

Broadscope licenses may authorize use of any byproduct material by anyone in accordance with review and approval procedures and criteria established by the Radiation Safety Committee (Type A) or the Radiation Safety Officer (Type B). Therefore, individuals are not specifically named on the license as users nor are the radionuclides limited to narrow, specific uses. These types of licenses are intended for licensees that cannot operate under a more limited specific license without seriously disrupting their programs.

Except for activities specifically excluded from broadscope licenses by paragraph 641-39.4(28)"e", a broadscope license can include any licensed material the applicant needs and for which it qualifies. The exclusions stated in paragraph 641-39.4(28)"e" provide that, unless specifically authorized by other parts of the regulations, persons licensed under broadscope licenses may not:

1. Conduct tracer studies in the environment involving the direct release of radioactive material (field users).
2. Possess, use, transfer, or import 100,000 curies (3.7×10^{15} Bq) or more of byproduct material in sealed sources for irradiation of materials.
3. Conduct activities licensed under 641 Chapter 39 (manufacture or transfer of exempt and generally licensed items), 641 Chapter 45 (radiography), 641 Chapter 41.2 (medical-human use).
4. Add or cause the addition of byproduct material to any food or other product designated for ingestion or inhalation by or application to a human being.

The applicant should:

- be familiar with the IDPH regulations, requirements, and procedures;
- have demonstrated a need for a broadscope license to avoid numerous amendments for multiple materials, uses, and users; and
- have established a good performance record with the IDPH both in licensing and inspection.

The provision for five (5) years of operation under a limited specific license is to be used as guidance, not as an absolute requirement. An exception to this suggested minimum experience of five (5) years will be considered on the merits of a licensee who has a program of sufficient size, variety, and frequency of amendments that genuinely warrants the flexibility of a broadscope license. Early consideration (less than five years of operation) for a broadscope license may be appropriate if, for example, the Radiation Safety Officer and some members of the proposed Radiation Safety Committee have had appropriate experience with other broadscope licenses. On the other hand, frequent amendments that indicate a turnover of essential personnel (not the additions of personnel for program growth) would raise questions of adequate continuity and organization for administration of a broadscope license. There must be close communication between the regions, inspection, and licensing staffs when evaluating new requests. The use of a pre-licensing visit before issuance of any new broadscope licenses should also be considered.

1.3 -- MEDICAL INSTITUTION BROADSCOPE LICENSES

When evaluating research requests, broadscope licenses that involve human use for both medical and non-medical research require

- establishment of specialized subcommittees
- U.S. Food and Drug Administration approved committees, e.g., Radioactive Drug Research Committees (RDRC), Institutional Review Boards (IRB),

Appendix N provides a general flow diagram that may be used in determining the need for a human use subcommittee and/or one or more of the FDA (or other Federal agency) Committees to supplement your RSC and its review process.

A broadscope medical Type A license is intended to accommodate those organizations involved in an extensive radioactive material program where the demand is great for a variety of radionuclides and uses. Broadscope medical licenses may authorize use of any byproduct material in medical research activities by anyone according to review and approval procedures and criteria established by the Radiation Safety Committee.

Therefore, individuals are not specifically named on the license as users nor are the radionuclides limited to narrow, specific uses. These licenses are intended for licensees that cannot operate under a more limited specific license without seriously disrupting their programs. This guidance pertains only to medical broadscope licenses that will maintain the medical broadscope program because they meet the following criteria:

a. The licensee has an active medical research program;

b. The medical research program involves human use and may include use of radioactive drugs approved for use by the U.S. Food and Drug Administration or a Radioactive Drug Research Committee (RDRC).

c. The licensee has and uses an Institutional Review Board (IRB) and/or other appropriate review committees to approve the studies based on ethical considerations, scientific merit, and radiation safety;

d. The licensee uses a broad-spectrum of byproduct materials and has demonstrated a need for any byproduct material with atomic numbers between 1-83 inclusive;

e. The licensee has sufficient staff, facilities, and resources to protect health and safety as determined by IDPH staff; and

f. The Radiation Safety Committee is composed of members who demonstrate sufficient ability by training and experience to name authorized users and approve facilities and new procedures.

Since broadscope medical licensees typically have committee members qualified in radiopharmacy, chemistry, dosimetry, nuclear medicine, etc., they are generally exempted from the provisions of sections 641-41.2(15)"a", 641-41.2(31), (33), (37), (41), and (43). However, since the radiation safety procedures related to medical use normally do not in themselves involve research, you should commit to possessing and using byproduct material for medical use according to the criteria in other sections of 641 Chapter 41.2. You should commit to instituting procedures equivalent to those described in Iowa Department of Public Health Medical Regulatory Guide.

Broadscope medical licensees who want to approve physicians, dentists or podiatrists to use byproduct material for medical purposes, must commit to evaluating physician using criteria equivalent to that detailed in 641 Chapter 41.2. You should submit an amendment to your license, requesting IDPH review of physicians whose training and experience are not equivalent. You should also describe the mechanisms used to record this review.

1.4 -- APPLICABLE REGULATIONS

Regulations pertaining to this type of license are found in Chapters 38, 39, 40, 41, and 45 of the "Radiation Machines and Radioactive Materials Rules." You may go to www.idph.state.ia.us and click on Health Protection and Environmental Health. Follow the links to the Bureau of Radiological Health. The regulatory guides can be found by further following the links to Radioactive Materials.

1.5 -- AS LOW AS REASONABLY ACHIEVABLE (ALARA PHILOSOPHY)

Paragraph 641-40.1(3) states "...Every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA)." As an applicant, you should consider the ALARA philosophy in the development of plans for work involving radioactive material.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that

commitment with adequate resources. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of by-product material is required by 641-41.2(9) to review uses for safety and ALARA considerations.

The Committee, the Radiation Safety Officer (RSO), and management are required to audit the by-product material program to ensure the continued safe use of by-product material. In addition to being a member of the Committee, the RSO serves as a technical consultant to the Committee and is responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Several NRC publications that contain background information on ALARA philosophy and its applications are available from the IDPH upon request. Applicants are required to consider the ALARA philosophy for work with radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing form 229-0514, "Application for Radioactive Materials License." You should complete Items 1 through 5, and 14/15 on the form itself. For Items 6 through 12, submit the required information on supplementary pages. Identify each sheet or document with the item number on the application. All typed papers, sketches, and, if possible, drawings should be on 8 1/2 x 11-inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8 1/2 x 11 inches.

You should complete all items in the application in enough detail for the IDPH to determine that your equipment, facilities, training, experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the public in the IDPH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of propriety information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by IDPH.

Retain a copy of your application for yourself because the license will be issued based on the statements and representations in your application and any supplements to it as well as the requirements in the regulations. The statements and representations become enforceable as if they were regulations.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on IDPH Form 229-0514. The appendices to this guide serve to

- provide additional information on certain subject areas;
- provide a model procedure the applicant may adopt in response to an item on the application form; or
- provide an outline the applicant may use to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, or call 515-281-3478.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual applicant, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 1.b.

ITEM 1.b. -- LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. If by-product material is to be used at more than one location, you must give the specific address of each location. In items 6 through 12 of the application, describe the intended use and the facilities and equipment at each location.

ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions only about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only. It would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to the CEO with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee is provided in writing to IDPH.

ITEM 3. -- LICENSE INFORMATION

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated for amendments or renewals.

ITEM 4. -- INDIVIDUAL USERS -- THEIR TRAINING AND EXPERIENCE

Individual users are not listed in a broadscope license. The RSC (Type A) or RSO (Type B) license approves all users. The requirements are outlined in Appendix E. For medical broadscope licenses, individual users using material listed in 641-41.2(31), (33), (37), (41), and (43) shall meet the applicable requirements of 641.41.2(68) through (72).

ITEM 5. -- RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using Supplement A. Even if the licensee employs a consultant as RSO, the licensee is still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations that are considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals and in a safe manner.

The RSO or the Radiation Safety Officer's staff should approve or place all orders for radioactive material and ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.

The RSO's qualifications and duties are discussed in more detail in Appendix B. Review this appendix and submit the applicable information.

ITEM 6. -- RADIOACTIVE MATERIAL AND ITEM 7. -- PURPOSE

Describe the byproduct material you wish to possess by isotope, chemical or physical form. Make a separate line entry for each item. Number each line entry consecutively. You should state the maximum quantity of each radioactive material you wish to possess at any one time and the total cumulative quantity for all materials (expressed in curie, millicurie, etc.). Your possession request should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-contained irradiators, instrument calibrators, and medical applications (both routine and non-routine).

You do not have to list certain calibration and references sources exempted in 39.4(22)"g" or 41.2(20). For sealed sources for temporary implants used in 41.2(43) and sources used in 41.2(41), list manufacturer and activity.

The maximum quantity for each individual nuclide and total cumulative possessions should be commensurate with your needs, facilities, procedures, and personnel. If certain nuclides will be needed in much larger quantities than others, they should be listed separately rather than increasing the quantity of all nuclides to include these larger quantities. A separate listing is also required for sealed sources needed in quantities larger than requested (e.g., bone mineral analyzers, sealed sources, brachytherapy after-loaders, portable and non-portable gauging devices). Large activity sealed sources used in devices (e.g. self-contained irradiators, panoramic irradiators, and instrument calibrators) should be described by manufacturer and model number under Item 6b.

If relatively more hazardous nuclides (e.g., Strontium-90, Americium-241) are needed only in smaller quantities, they should be listed separately. The maximum quantities of nuclides with atomic numbers above 83 also should be stated separately. When establishing both individual nuclide and total maximum quantities, all materials possessed under your license should be included, i.e., materials received awaiting use, materials in use/process, and that categorized as waste awaiting disposal.

The atomic number 83 is designated an upper limit because specialized facilities, instrumentation, and containment for transuranics (alpha and neutron emitters) must be considered. Radionuclides above 83 may be included in a broadscope license, but are usually listed separately in the application and license. Exceptions may be considered on their merits. For example, it may be appropriate to consider a separate listing of atomic number 84 and up (as appropriate) with a different possession limit than for atomic numbers 1 to 83.

Describe in general terms the purposes for which you will use licensed material and explain why you need a broadscope license rather than amendments to an existing specific license. The uses should be consistent with your prior licensed activities. Although the IDPH staff only needs a general description of your activities, you should provide sufficient information to enable them to have a clear understanding of each use. The information provided regarding "Purpose of Use" is understood by the IDPH staff as a self-imposed limitation contained within your application.

If a broadscope licensee desires to initiate a use other than that described in its application, it would be necessary to submit an amendment to your license to modify/expand the "purpose of use." In addition, if the newly added purpose of use includes a relatively unique or specialized activity (e.g. sealed source fabrication), you may be required to submit the criteria used by the RSC in evaluating in-house requests for such use.

Applicants requesting authorization to distribute material possessed following 641 Chapter 39 must request and obtain a separate license for such activities.

If your program under present and previous licenses does not show a need for the flexibility of a broadscope license, a continuation of conventional specific licensing may be more appropriate. Alternatively, the applicant should provide information regarding expansion plans that would subsequently warrant a broadscope license.

Note that 641-39.4(28)"e" lists a number of activities that broadscope licensees may not do unless specifically authorized pursuant to other parts of the regulations. Licensing staff sometimes require separate applications and licenses for activities for which there are separate licensing guides, or that are licensed under 641 Chapters 39, 41.2 and 45.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description or chart of the overall organization pertaining to the radioactive materials program, which specifies the name and title of each individual who has responsibility for management or supervision of the program.

NOTE: ITEMS 9. through 12.

Your response to these items should consist of one sentence that says that you will follow the model procedure in Appendix __ in IDPH Regulatory Guide Broadscope Regulatory Guide; that you have enclosed your procedure for review; or “NA" for "not applicable." Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your response to Items 9 through 12 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to name specific individuals, equipment by serial number, room numbers, or other site-specific information, there is no need to submit that procedure for review. Other than hot labs, procedures should allow for replacement of identical equipment, personnel, and administration rooms.

ITEM 9. -- TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

A broadscope licensee must provide initial and refresher training to all individuals who will use, or may be exposed to, radioactive material. Examples of employees who will need training are authorized users, laboratory supervisors and technicians, radioactive material incinerator and waste compactor operators, housekeeping, nursing, and security personnel and radiation safety office staff. It is understood that each training program will vary from licensee to licensee. The detail and content will be dependent upon:

- the scope of the program (i.e., Type A, B or medical broadscope license)
- possession limits
- type of isotopes used
- size of program in terms of number of laboratories and users,
- laboratory classification scheme
- types of studies being performed

The IDPH staff recommends that broadscope licensees develop a system for retraining authorized users, laboratory supervisors and technicians that is performance-based (i.e., 'hands-on'). Your application should describe the program in place for training your staff. Appendix E provides an example of a broadscope training program, which is acceptable to IDPH staff.

ITEM 10. -- FACILITIES AND EQUIPMENT

Describe any facilities and equipment that are essential to the license being applied for. Facilities and equipment used for special applications where the impact upon workers or the public could be significant if radioactive material were released accidentally may be required to be specifically identified. These would include

- room irradiators
- specialized iodination facilities
- alpha laboratories
- large scale waste processing and storage facilities (including decay-in-storage locations, incinerators, compactors, liquid reclamation processors, etc.)
- individual laboratories processing 100 millicuries (3.7 GBq) or more of radioactive materials per experiment or process
- nuclear pharmacies
- specifically designed therapy rooms and/or storage areas (radiopharmaceutical and/or sealed sources)

Your administrative procedures for internal control of users under the broadscope license should include provisions for determination that your facilities and equipment are adequate for all proposed uses. Your application should include a laboratory or facility classification scheme that relates toxicity and quantity of radioactive material. Health physics and industrial hygiene professional organizations have developed classification schemes used in assessing minimum needs (e.g., equipment and facilities, user training, personnel monitoring, surveys) versus the hazard and quantity of byproduct materials to be used. IDPH staff recommends that applicants consider the development of such a classification scheme, since all aspects of the radiation safety program can be correlated to it. Each applicant's scheme should be based upon the types and quantities that are anticipated. The criteria used to develop the classification scheme should be made into a manual and provided to each RSC member for use when evaluating requests.

ITEM 10.1 -- OTHER EQUIPMENT

Describe the radiation detection and monitoring equipment available to both the radiation safety office and authorized users. List the type and number of instruments available (e.g., ion-chambers, G-Ms, air samplers, liquid scintillation counters). In addition, describe your instrument calibration program including calibration procedures and frequency. If a vendor will calibrate instruments, specify the vendor name, or confirm that such calibrations will be done by persons specifically authorized by the NRC, IDPH, or another Agreement State to perform such services.

ITEM 10.2 -- TRANSPORTATION

All licensees are required to comply with 641-39.5 regarding transportation of licensed material. If the licensee acts as a shipper or carrier of radioactive material, the applicant should provide a description of the mechanisms or procedures used to assure the following:

A. Transportation of radioactive material is in accordance with 641-39.5. Procedures should include:
   1. Approved packages
   2. Appropriate labeling
   3. Proper surveys
   4. Complete and accurate shipping papers
   5. Bracing of packages
   6. Security provisions
   7. Emergency procedures

B. Training in transportation regulations and emergency procedures for drivers and technologists. Documentation of this training should minimally include dates, topics discussed, attendees and instructor's name.

C. Quarterly management audits of transportation documentation and temporary job site activities (i.e., shipping papers, survey reports, etc.).

D. Emergency procedures that van drivers shall follow in case of an accident involving licensed material in transport shall be maintained in the vehicle during transport. Emergency procedures should minimally include posting the area, maintaining surveillance, and notifying the RSO. A copy of these procedures must be included in the application.

E. Procedures for handling radioactive waste during transport. Describe the method of storage and final disposal.

ITEM 11. -- RADIATION SAFETY PROGRAM

The formal requirements for a radiation safety program under a broadscope license are contained in 641-39.4(28). To ensure safe operations, this regulation requires applicants to have engaged in a reasonable number of activities involving the use of byproduct material and to have established administrative controls and provisions related to

- organization management
- procedures
- record keeping
- material control
- accounting
- management review

Your radiation safety program description should be in narrative form and include all the elements identified below.

ITEM 11.1 -- MANAGEMENT CONTROLS AND RESPONSIBILITIES

ITEM 11.1.1 -- SENIOR MANAGEMENT

A broadscope license is issued by the IDPH to accommodate those institutions involved in an extensive radioactive material program where the demand is great for a variety of radionuclides and uses. Therefore, IDPH grants significant latitude to licensee management to develop and implement an appropriate radiation safety program. Consequently, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Appendix C discusses the role of management in broadscope licenses.

ITEM 11.1.2 -- RADIATION SAFETY COMMITTEE

You are required to establish a Radiation Safety Committee (RSC) following 641-39.4(28)"b"(3). The RSC is responsible for establishment of appropriate policy and procedures to assure control of procurement and use of byproduct material, completion of safety evaluations of proposed uses and users, and overall development and implementation of the radiation safety program.

Appendix D discusses the Radiation Safety Committee membership and responsibilities in detail.

The licensee should submit the following:

- A description of the duties and responsibilities of the Radiation Safety Committee, including

  The review and approval process for program and procedural changes prior to implementation;

  Implementation process of program and procedural changes;

Audit of licensed operations to determine compliance; and

The actions taken when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

- A description of the documentation for specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered before approval of the change.

ITEM 11.1.3 -- RADIATION SAFETY OFFICER

Broadscope licensees must have a Radiation Safety Officer (RSO) who is qualified by training and experience in radiation protection and who is routinely available for advice and assistance on radiological matters. The RSO is a member of the Radiation Safety Committee and works closely with the RSC and executive management in implementing the radiation safety program. The RSO must ensure that radiation safety activities are being performed safely and according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of radioactive material and/or radiation producing machines. It is essential that the RSO have the authority to terminate any activity in which health and safety appear to be compromised without consulting with executive management or the RSC, if required.

The RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSO performs audits or oversees audits of all areas of use to ensure work is done in accordance with the license, regulations, and user authorizations. The duties of the RSO may not be transferred. Many tasks and duties associated with managing the radiological program may be assigned or delegated to other qualified individuals; however, the responsibility for those tasks and duties is with the RSO. IDPH recognizes that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods of time (e.g., to attend conferences, for vacation, or for illness). However, this should not occur for extended or indefinite periods of time. Consideration should also be given to how this individual would be contacted in the event of an emergency.

When selecting the RSO, the applicant should keep in mind the duties and responsibilities of the position, select an individual who is qualified to serve as RSO. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with by-product material under his or her responsibility. IDPH recognizes that an RSO cannot be an expert in all areas that might involve a broadscope program. However, the RSO should be qualified by training and experience to conduct the required duties. Management should ensure that sufficient time is allocated to the individual selected as RSO to carry out the responsibilities of the position.

ITEM 11.1.4 – RADIATION SAFETY OFFICE STAFF (RSOS)

A staff of health physics professionals who assist in the maintenance and control of the licensed program support the RSO. The number and qualifications of professionals will vary with the scope of the broadscope license program. Your application should include a description of the duties and responsibilities of the RSOS and an assessment regarding staffing levels and qualifications of this support staff, if applicable. The assessment should be sufficient to demonstrate that the technical staff is adequate to implement, support, and oversee your proposed radiation-protection program. If current staffing is not what you consider adequate, a projected timetable when full staffing will be achieved should be included. A projection of future needs would also be useful.

ITEM 11.2 -- LICENSED MATERIAL INVENTORY AND ACCOUNTABILITY

A broadscope license authorizes possession and use of a vast array of radionuclides in relatively liberal quantities, typically for medical use, research, and research and development. These liberal possession

limits, combined with a large number of individual users and locations of use can create material inventory and accountability problems, if not properly managed. Consequently, applicants should develop and maintain a strong inventory and accountability system.

The institution should have the capability to continually track incoming shipments of licensed material, and account for material usage, decay, transfer, and disposal. A licensee's inventory and control system should have the capability to assure that licensed possession limits are not exceeded and that material is accountable throughout the institution at any given time. Sufficient staff and equipment should be devoted to the inventory and accountability control program.

Your application must include a description of your inventory, control and accountability program for licensed material.

Licensed materials that may be transferred from one department, laboratory or authorized user's control should have prior approval from the RSO or the RSOS. A written transfer procedure should be developed by the RSO to ensure that transfers are done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers. You should submit your internal transfer procedures.

ITEM 11.3 -- FIELD USE OF BYPRODUCT MATERIAL

If you desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies, the information outlined in Appendix Q must be included with your application. Such field studies must be specifically authorized in your license.

ITEM 11.4 -- ADDITIONAL ELEMENTS OF A RADIOLOGICAL PROGRAM

In addition to the information above, review the following appendices carefully. Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate “not applicable.”

Appendix A:	Model Program for Maintaining Occupational Radiation Exposure ALARA
Appendix B:	Radiation Safety Officer (RSO)
Appendix C:	Senior Management Responsibilities
Appendix D:	The Radiation Safety Committee
Appendix E:	Concepts and Elements of a Broadscope License Training Program
Appendix F:	Model Personnel Exposure Monitoring Program
Appendix G:	Model Procedure for Leak-Testing Sealed Sources
Appendix H:	Model Rules for Safe Handling of Radioactive Material
Appendix I:	Model Spill Procedures
Appendix J:	Model Procedure for Area Surveys
Appendix K:	Safety Evaluations of Proposed Uses/Users
Appendix L:	Administrative Procedures
Appendix M:	Audits and Appraisals
Appendix N:	Flow Diagram to Aid in Determining Licensee's Committee Membership Need Relating to Human Research
Appendix O:	Reserved
Appendix P:	Financial Assurance, Recordkeeping, Decommissioning Plans, and Emergency Plans
Appendix Q:	Information Required for Field Use of Byproduct Material
Appendix R:	Radioactive Materials Used in Animals
Appendix S:	Incineration Guidelines for Material Licensees
Appendix T:	Model Procedure for Waste Disposal
Appendix W:	Definitions and Acronyms

ITEM 12. -- WASTE MANAGEMENT

You should describe your methods for disposal of radioactive waste. Your application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from non-radioactive, short half-life from long, liquid from solid waste).

Submit your procedures for waste disposal. See Appendix T. Be sure to include a procedure for all material listed in Item 6.

ITEM 13. -- LICENSE FEES

1. An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at www.idph.state.ia.us. An application received without a fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.

2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.

3. Review 39.4(26) "Financial Assurance and Recordkeeping for Decommissioning." Submit financial assurance as described or provide information that exempts the facility.

ITEM 14, 15 -- CERTIFICATION

If the application is for a private practice, a senior partner or the president must sign it. If the application is for an institution, hospital, or medical center, it must be signed by its director or chief executive officer. Identify the title of the office held by the individual who signs the application.

If the president, director, or chief executive officer wishes another to sign the application, a delegation of authority must be enclosed. The delegation of authority should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later.

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. See 641-41.2(4) for the specific requirements. An application for an amendment must be filed on IDPH Form 299-0514 or as a letter and must be signed by the person delegated in Item 14/15. The appropriate fee must be included.

The licensee may not place into effect any amendment until receiving written verification from the IDPH that the amendment has been approved.

5. RENEWAL OF LICENSE

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by the IDPH as provided for in paragraph 641-39.4(34). The application for the renewal should not reference material that was previously submitted.

If you do not wish to renew your license, you must dispose of all licensed radioactive material you possess in a manner authorized by 641-39.4(33)"d" before the expiration date of your license. Only then may you request that your license be terminated. If you cannot dispose of all material before the expiration date, you

must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating IDPH regulations that do not allow you to possess licensable material without a valid license.

6. IMPLEMENTATION

The information in this regulatory guide is guidance, not requirement. The IDPH reviews each application to ensure that users of by-product material are capable of complying with IDPH's regulations. This guide provides one set of methods approved by the IDPH for meeting the regulations and represents the minimum acceptable standards.

7. INSPECTIONS

IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule. (For example, the routine inspection for a licensee with Irradiated Gemstones would be scheduled four years after the initial inspection.)

APPENDIX A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

In addition to 641-41.2(7)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix A to IDPH Broadscope Regulatory Guide."

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model program. Medical licensees should carefully review the requirements of 641-41.2(7). Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A."

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

   a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC), if applicable, and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far as below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. REVIEW OF PROPOSED USERS AND USES

   a. Review of proposed users and uses

      1. The RSC will thoroughly review the qualifications of each applicant with respect to the types, quantities, and methods of use. The RSC should ensure that the applicant will be able to take appropriate measures to maintain ALARA.
      2. When considering the use of by-product material, the RSC will review efforts of the applicant to maintain exposure ALARA.
      3. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of authority

1. The RSC will delegate authority to the RSO for enforcement of an ALARA program.
2. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of the ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
2. The RSC will perform a quarterly review of occupation radiation exposure with particular attention to instances in which the investigational levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

3. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. RADIATION SAFETY OFFICER COMMITMENT

a. Annual and Quarterly Review

1. Annual review of the radiation safety program. The RSC, along with the RSO, will perform a review of the radiation safety program for adherence to ALARA concepts. Appendix M discusses audits in more detail.
2. Quarterly review of occupational exposures. The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of section number 5 of this appendix.

b. Education Responsibilities for ALARA Program

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. The RSO will ensure that these individuals are informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
3. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

d. Reviewing Instances of Deviation from Good ALARA Practices:

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

4. AUTHORIZED USERS COMMITMENT

a. New methods of Use Involving Potential Radiation Doses

1. The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
2. The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals
1. The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
2. The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

5. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES[1]

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on IDPH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 641-40.100. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the investigational Level I.

b. Personnel doses equal to or greater than Investigation Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. However, the Committee will review each such dose

[1] IDPH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the RSC at its first meeting following completion of the investigation. In addition, a copy of the individual's Form IDPH 588-2834 “Occupational Exposure Record for Monitoring Period” and 588-2833 “Cumulative Occupational Exposure History” or its equivalent will be provided. The details of these reports will be included in the RSC minutes.

d. Re-establishment of investigational levels to levels above those listed in Table I.

In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

TABLE 1

INVESTIGATIONAL LEVELS

	Investigational Levels (mrems per month)	
	Level I	Level II
1. Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
2. Skin of whole body, extremities	2000	4000
3. Lens of eyes	600	1200

APPENDIX B

THE RADIATION SAFETY OFFICER (RSO)

Broadscope licensees are required to appoint a Radiation Safety Officer (RSO) pursuant to 641-39.4(28)"b"(3) and 39.4(28)"c"(2). The RSO is responsible for oversight of the day-to-day radiation protection program established by the RSC, and communicating with senior management and the RSC regarding program implementation and compliance status.

The RSO should have an academic degree in physical or biological science or engineering, specific training in radiation health sciences and considerable professional experience (generally about five years) with a broad spectrum of radioactive materials. The RSO's professional experience should include the application of this training to the management and administration of a radiation safety program related to the types, quantities, and uses of the radioactive material to be used under this license. A previous background in program and staff management is also desirable.

List and describe the training and experience of the RSO in radiation protection and with radiation and radioactive materials. If he or she is not a full-time paid employee of your organization, please provide the individual's affiliation with your institution and state how many hours per week the individual will be available to oversee your IDPH-licensed program. Also specify provisions for contacting this individual during emergencies, off-hour contact and a general description of his or her other obligations. Generally, the IDPH staff does not consider the use of consultants or part-time RSO's as acceptable for broadscope license programs. The RSO should report to top management in a staff capacity, have ready access to all levels of the organization, and the authority to immediately terminate a project that is found to be a threat to health, safety, or property.

A statement should be included delineating RSO duties, responsibilities, and authority for carrying out the radiation safety program. You should list the responsibilities and duties of the RSO in your application. The extent of these responsibilities and duties will depend on the scope of the proposed broadscope license.

RSO's responsibilities and duties should be commensurate with the scope of the licensee's program. The duties listed are those that are usually performed by the RSO and his or her staff and that constitute good practice for conducting a program in compliance with the specific regulatory requirements and license conditions. Except in medical and industrial radiography facilities, the duties of the RSO are not specified in the regulations. The RSO's duties and procedures, therefore, may not correspond to each item on the list of suggested duties. However, there should be assurance that the RSO understands and is competent to manage the program under a broadscope license. A complete description of the RSO's qualifications and duties is an important part of such assurances. A statement of duties along with training, experience, past performance, is therefore necessary. Less than five (5) years of experience and prior performance may be acceptable if the applicant's qualifications appear adequate for the scope of the proposed broadscope license. An RSO should have an essentially full-time commitment to radiation safety and other related duties. A key in the review is prior experience in the oversight of a materials program, i.e., either as a RSO or assistant RSO.

SPECIFIC DUTIES AND RESPONSIBILITIES OF A BROADSCOPE LICENSE RADIATION SAFETY OFFICER

1. Surveillance of overall activities involving radioactive material, including routine monitoring and special surveys of all areas in which radioactive material is used.

2. Determine compliance with rules and regulations, license conditions, and the conditions of project approvals specified by the Radiation Safety Committee.

3. Monitor and maintain absolute and other special filter systems associated with the use, storage, or disposal of radioactive material.

4. Furnish consulting services on all aspects of radiation protection to personnel at all levels of responsibility.

5. Receive, deliver, and open all shipments of radioactive material arriving at the institution and package, ship all radioactive material leaving the institution.

6. Distribute and process personnel monitoring equipment, determine the need for bioassays, evaluate bioassay records, and notify individuals and their supervisors of exposures approaching maximum permissible amounts and recommend appropriate remedial action.

7. Conduct training programs and otherwise instruct personnel in the proper procedures for the use of radioactive material before use, at periodic intervals (refresher training) and as required by changes in procedures, equipment and regulations, etc.

8. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and maintenance of waste storage and disposal records.

9. Store radioactive materials not in current use, including wastes.

10. Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.

11. Maintain an inventory of all radioisotopes at the institution and limit the quantity of radionuclides at the institution to the amounts authorized by the license.

12. Stop an activity that is found to be a threat to health or property.

13. Supervise decontamination and recovery operations.

14. Maintain other records not specifically designated above, e.g., receipt, transfer, and survey records.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with rules. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to request amendment changes and raise issues with the Iowa Department of Public Health, Bureau of Radiological Health at any time.

_____
Signature of Management Representative

_____
Date

I accept the above responsibilities,

_____
Signature of Radiation Safety Officer

_____
Date

cc: Affected Department Heads

APPENDIX C

SENIOR MANAGEMENT RESPONSIBILITIES)

641-39.4(28)"b" and "c" require that Type A and B broadscope license applicants, respectively, establish administrative controls and provisions relating to organization and management, including management review, necessary to assure safe operations.

Licensee's management responsibilities and liabilities are often under-emphasized and misunderstood by employees and managers. Type A and medical broadscope licensees are required to establish a Radiation Safety Committee that represents management when reviewing and approving safety evaluations. Therefore, senior management must delegate to the RSC and RSO, in writing, the requisite authority to communicate with, enforce and direct your personnel regarding IDPH regulations and/or license provisions. It is also essential that the institution devote sufficient financial resources as necessary to support the radiation protection program.

Your application should discuss senior management oversight and mechanisms used by management to ensure adequate control over licensed broadscope activities. The IDPH expects senior management oversight to consist of regular meetings with the Radiation Safety Committee, Radiation Safety Officer and support staff, and periodic management audits of the program to assure safe operations and compliance with regulatory requirements. The audit program should include mechanisms to correct and resolve identified problems in an expeditious manner (program audits are discussed in Appendix M).

Your application should include an organizational chart depicting your management structure. Indicate the reporting paths and flow of authority. Include your statement empowering the Radiation Safety Committee, outlining its authority to oversee the licensed program, the responsibility for control and direction of radiation safety, and the Radiation Safety Officer.

The operational oversight for a Type B broadscope license program is specified in 641-39.4(28)"c"(2)"1". It states in part"...appointment of a Radiation Safety Officer who is qualified by training and experience…." If you are applying for a Type B license, as indicated above for the Type A and RSC, your application should include an organizational chart and management statement describing the RSO's authority.

APPENDIX D

THE RADIATION SAFETY COMMITTEE (RSC)

The RSC should consist of the Radiation Safety Officer; at least one representative of management; and at least one technical person from each of the departments, groups, or activities that will use radioactive materials under the broadscope license. Each technical member of the RSC should have training and experience in the use of radioactive materials and radiation safety; however, this background need not be as extensive as that of the RSO. The administrative member or members of the RSC should ensure management support of the radioactive materials program and due consideration of the financial, legal, and business interest of the organization. Administrative members of the RSC need not have a background in radiation safety. Members with less important safety functions, e.g., student representative, nursing representative, administrative representative, etc., may be listed by title and minimum qualifications.

The identity of the committee chairperson and each member of the RSC who has an essential radiation safety function and their positions in your organization must be specified. Besides the RSO and Chairperson, individuals from each area of use should be named as a committee representative. The IDPH staff considers the RSO, Committee Chairperson, and the technical committee members as the "voting membership" of the RSC, i.e., individuals empowered to act upon proposals for the use of radionuclides. If fewer members than compose the full committee are empowered to act for the committee, the number of members constituting a quorum, as well as their names or fields of expertise, should be specified. The minimum staff considered acceptable for a quorum would be:

- Chairperson,
- RSO,
- A management representative,
- A person(s) representing the department/area from whom the radioactive material request originated, and
- Any other committee member whose field of expertise is necessary to assure all safety aspects have been addressed

Your application should describe RSC meeting frequency and criteria, and include a specific and detailed description of the control functions of the committee and the administrative procedures by which these functions are carried out.

1. Meet as often as necessary to conduct business but not less than quarterly.

2. Conduct periodic reviews and audits of the radiation safety program.

3. Devote sufficient time with the Radiation Safety Officer (RSO) and the Radiation Safety Office Staff (RSOS) reviewing records, reports from the RSO, results of IDPH inspections, written safety procedures to ensure the adequacy of the institution's management control systems. Examples of program review include, but are not limited to the following:

    a. Periodic review of protocol/user permits issued by the RSC (e.g., review of such permit at 1-2 year intervals).
    b. Review of letters of agreement with off-site emergency response agencies.
    c. Review of procedures for controlling and maintaining inventories, procurement of radioactive material, individual user and institutional cumulative possession limits, transfer of radioactive materials within the institution, and transfer of radioactive material to other persons/licensees.
    d. Reviews of audit findings (of RSC approved users and facilities) by the RSOS.

3. Conduct safety evaluations of proposed users and uses. Procedures and criteria established for making safety evaluations of proposed uses of radioactive material are described in Appendix M.

4. Develop procedures and criteria for training and testing of each category of worker. (Refer to Appendix E.)

5. Establish methods for maintaining records of the committee's proceedings that include safety evaluations of proposed users and the uses of radioactive materials. Submission of these documents would be useful in understanding your program. Although specific criteria and procedures are required as a basis for evaluating the license application, the applicant may specify that certain portions of the documents may be revised without prior notification of the IDPH staff. For example, the applicant may specify in the application that the institution will make the following changes without notifying the IDPH:
    - changes dictated by IDPH rule changes,
    - changes in internal management forms or specific dates,
    - changes in contractors for bioassay, waste disposal or for servicing and calibrating personnel dosimeters,
    - changes in references to particular pieces of equipment, etc.

    By careful use of the technique, the applicant can avoid the necessity for frequent license amendments.

6. Develop safety manuals as necessary to ensure proper program implementation and good health physics practices.

APPENDIX E

CONCEPT AND ELEMENTS OF A BROADSCOPE LICENSE TRAINING PROGRAM

1. Concept

The Radiation Safety Committee (in consultation with the Radiation Safety Officer (RSO)) is responsible for developing and instituting your radiation protection program. Your program for training should provide a commitment to initial training, retraining, or continuing education. The type and amount of instruction may be structured based on past training and experience, and commensurate with potential radiological health protection problems in the area(s) the employee is expected to work. Performance based training and continuing education, based on site specific (laboratory classification) criteria are considered important aspects of the training program.

2. Elements

All radiation workers must receive instruction in accordance with 641-40.111(136C) before beginning work with licensed materials. This instruction may be in the form of an orientation session led by the RSO or a qualified staff member under his/her direction. This orientation includes the following subjects:

a. Applicable regulations and license conditions

b. Areas where radioactive material is used and stored

c. Potential hazards associated with radioactive material

d. Appropriate radiation safety procedures

e. Special in-house rules

f. Individual's obligation to report unsafe conditions to the RSO and/or applicable authorities

g. Appropriate response to emergencies or unsafe conditions

h. Worker's right to be informed of occupational radiation exposure and bioassay results, and

i. Locations where copies of pertinent regulations, licenses, and other material required by regulations are posted or made available.

3. Authorized Users

In addition to the above, the training and experience of authorized users should be at least equivalent to that specified in 641-39.4(28)"d"(2):

a. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

b. At least 40 hours of training and experience in:
   - the safe handling of radioactive materials
   - the characteristics of ionizing radiation
   - units of radiation dose and quantities
   - radiation detection instrumentation
   - biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used

The above description is for users authorized under a Type C license, which generally involve use of radioactive material in microcurie to low millicurie quantities. Therefore, your program of instruction should be correlated to your laboratory classification scheme. The above description would be adequate for Type C laboratories; however, additional training would be required for the Type A and B laboratories. Training to achieve the requirements of item b. may be provided by the Radiation Safety Officer or his/her qualified staff. Such training should be documented. Alternatively training specified in item b. may have been obtained at a different institution; however, its scope and adequacy should be documented and approved by the Radiation Safety Committee.

Training and experience for physician authorized users must meet the criteria outlined in 641 Chapter 41.2.

4. Radiation Workers (Working Under the Supervision of an Authorized User)

In addition to 641-40.111(136C) instruction, each radiation worker supervised by an authorized user must receive specific documented instruction from the authorized user and the radiation safety office staff. The authorized user works directly with new staff until the authorized user is confident in the worker's abilities and understanding of IDPH regulations, license provisions and "in-house safety instructions. The authorized user is responsible for documenting the staff members completion of his/her instruction and certification of the worker's use of materials with limited supervision, i.e., not under his/her physical presence.

5. Other Radiation Workers and Ancillary Staff

The Radiation Safety Officer is responsible for developing a comprehensive radiation-training program. The training should be such that all technical radiation safety-staff, waste handlers, animal caretakers and ancillary staff (e.g., janitorial, housekeeping, security, nursing, etc.) understand the radiation hazards associated with their work. Training should also ensure that individuals are able to take appropriate actions to prevent unnecessary exposure. Special programs must be developed to instruct each different group with appropriate information in accordance with 10 CFR Part 19. This information may be conveniently incorporated into an institution's general safety orientation training program. For example, waste handlers need to be trained regarding both the radiological aspects of their duties as well as chemical and biological considerations.

6. Supplementary Continuing Education

To supplement education and to update training, the IDPH staff strongly recommends that the Radiation Safety Office issue regular (at least quarterly) radiation safety bulletins to authorized users and supervisors. The newsletter or memo should contain information important to the operation of the Radiation Safety Program and the safe handling of radioactive materials. This information should be required to be shared with the radiation workers and filed by the authorized user or supervisor along with the material authorizing the use of licensed material. Thus, it is the responsibility of the authorized user to provide evidence of the worker having received this and other pertinent information. It should be the responsibility of the Radiation Safety Office to audit this program.

7. Performance Based Training

In addition to basic didactic instruction, it is recommended that there be an emphasis on performance-based training. “Hands-on" training specific to the operations performed and the duties necessary to safely handle radioactive materials should be provided. The Radiation Safety Office should at least annually transmit specific instructions regarding the authorized user's responsibilities for providing training to their staff. An assessment of the comprehension and abilities of staff through random interviews with the authorized users and/or the radiation workers should be included in the Radiation Safety Audit program.

8. Emergency Procedure and Specialized Training

You should provide emergency procedures and specialized training and retraining to all applicable workers. All individuals who work with radioactive materials and frequent radioactive use and storage areas should be cognizant of emergency procedures applicable to their duties. Reliance on introductory orientation and review of tapes pertaining to accidents involving radioactive materials is normally not sufficient to assure appropriate, timely and adequate response to accident situations. Emergency procedure instruction is considered an excellent performance based training opportunity that could be incorporated into a retraining program.

Specialized, duty specific training should be provided to those individuals involved in such activities as radioactive waste handling and processing, incinerator operations, animal research, and those attending to radiotherapy patients.

Training records should include:

a. List of topics

b. Approximate time spent on each topic

c. Name of instructors and students

d. Dates of training

e. Written assessment or test for each student, documenting satisfactory completion of the training

f. Location and materials involved in the training provided

You should provide details of your in-house training program(s). Include in your description the following information:

a. The name(s), training, and experience of the individual(s) providing formal training

b. Outline and submit your program for providing the necessary instruction. Confirm that in addition to providing relevant instruction before assuming duties, appropriate training will be provided whenever there is a significant change in duties or regulations.

c. Confirm that continuing site-specific training will be provided. State the frequency and methods to be used.

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix E to IDPH Broadscope Regulatory Guide Regulatory Guide." You may use lectures, videos-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.111. Say on your application, "We have developed a training program for your review that is appended as Appendix E." Be sure to include the groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instructions have been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material

(whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel to be instructed:

1. All workers that might receive an occupational dose.
2. Ancillary personnel (e.g. clerical, housekeeping, security) whose duties may require them to work near radioactive material.

Frequency of instruction:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals will include the following subjects in addition to 40.111:

1. Applicable regulations and license conditions.
2. Licensee's in-house work rules.
3. Locations where you have posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 641-40.110.
4. Question and answer period.
5. Record of date of program, subject and attendees.

Written instruction prepared and distributed to all personnel should include:

1. Availability, selection, and use of laboratory apparel and safety-related equipment and devices such as lab coats, gloves, and remote pipetting devices.
2. Limitations and conditions to be met in handling liquid or uncontained (unencapsulated, dispersible, or volatile) radioactive materials and special lab equipment to be used in working with these types of materials. Instructions should explain when operations with materials should be confined to a radiochemical fume hood or glove box and should specify the use of appropriate shielding and remote handling equipment when energetic beta or gamma-emitting materials are to be used.
3. Performance of radiation survey and monitoring procedures for each area in which radioactive materials are to be used.
4. Safety precautions to be observed in movement of radioactive materials between buildings, rooms, and areas within rooms.
5. Safety requirements for storage of radioactive materials; the labeling of containers of radioactive materials; and posting and securing areas where radioactive materials are to be stored. This should include the storage of contaminated laboratory equipment such as glassware.
6. Requirements for posting of areas in which radioactive materials are used.
7. The availability and use of personnel monitoring devices.
8. Waste disposal procedures to be followed, including limitations on the disposal of liquid or other dispersible waste to the sanitary sewer and procedures for the collection, storage, and disposal of other wastes.
9. Maintenance of appropriate records.
10. Good radiation safety practices (See Appendix H)
11. Emergency procedures to cover spills, fires, release or loss of material, or accidental contamination of personnel. These should include actions to be taken in order to prevent or limit contamination, telephone numbers of individuals to be notified, instructions for re-entry and recovery operations for contaminated facilities.
12. Procedures for picking up, receiving, and opening packages.

13. If material will be used in animals, instructions on handling, control of wastes, cleaning, and security.

APPENDIX F

MODEL PERSONNEL EXPOSURE MONITORING PROGRAM

In addition to 641-40.36 and 40.37

You should describe the procedures and mechanisms established to control and monitor both internal and external radiation exposure. The procedures should include general criteria for all intended radionuclides of use and specialized criteria to address control and monitoring when higher levels of radionuclide activity or toxicity are used.

External Exposures

Specify the criteria used to assign personnel monitoring devices, i.e., film, TLD, or OSD whole body and extremity badges, direct reading dosimeters, and frequency of device processing for the various laboratory types. Indicate the supplier of your dosimetry system. This supplier is required to be NVLAP approved pursuant to 641-40.36(3)"a".

Internal Exposures

Describe the criteria used to determine the type and frequency of bioassay (both in-vivo and in-vitro) that will be performed to evaluate intakes. Guidance on bioassay programs is provided in NUREG/CR-4884, "Interpretation of Bioassay Measurements;" NUREG-0938, "Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure;" and Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

Describe the criteria used to set the type and frequency of routine surveys for airborne radioactive materials, e.g., air sampling of breathing zones and general work areas, hood and room ventilation air flow rate measurement and stack effluent sampling. The air sampling criteria should be incorporated into your laboratory classification scheme and provide enough detail that the IDPH staff is assured that appropriate steps will be taken to manage and monitor such exposures. Guidance on an acceptable air-sampling program is contained in the aforementioned Regulatory Guide 8.23.

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application. "We will establish and implement the model personnel exposure monitoring program published in Appendix F to Regulatory Guide Broadscope Regulatory Guide."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.36 and 40.37. Say on your application, "We have developed an exposure monitoring program for your review that is appended as Appendix F," and submit your monitoring program.

If personnel monitoring will not be used, you should submit calculations or documentation from radiation surveys that demonstrate that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 40.36 or 40.37.

MODEL PROGRAM FOR MONITORING EXTERNAL EXPOSURE

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film, TLD, or OSD whole body monitor that will be processed by a contract service on a (specify time period).
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor that will be processed by a contract service on a (specify time period).
4. All individuals who are exposed to radiation on an occasional basis such as secretarial personnel and service personnel who deliver packages will not normally be issued exposure monitors.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Monitoring devices should be stored in a cool, dry place away from possibility of accidental exposure.

BIOASSAYS

FREQUENCY OF REQUIRED BIOASSAY MEASUREMENTS

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual
- Retention and excretion characteristics of the Radionuclides
- Sensitivity of the measurement technique
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with 641-40.16(136C), which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10 per cent of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

ROUTINE MEASUREMENTS

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc) and the samples collected will vary according to the radionuclide and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements

should be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is >0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than two hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program, because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

SPECIAL MONITORING

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent Ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination
- Entry into airborne radioactivity areas without appropriate exposure controls
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity)
- Known or suspected incidents of a worker ingesting radioactive material
- Incidents that result in contamination of wounds or other skin absorption
- Evidence of damage to or failure of a respiratory protective device.

APPENDIX G

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources. If you or a contractor follows the model procedure, you may state in your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix (G.1 and/or G.2) to IDPH Regulatory Guide Broadscope Regulatory Guide."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed a leak-test procedure for your review that is appended as Appendix (G.1 and/or G.2)," and submit your leak-test procedure.

G.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
   b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
   c. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak-test period.

G.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie (185 Bq) for beta or gamma emitting radionuclides. For alpha emitting radionuclides, select an instrument that is sufficiently sensitive to detect 0.001 microcurie (37 Bq). For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a sodium-iodide crystal with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive. For alpha emitting radionuclides, a zinc-sulfide scintillation detector with a ratemeter or scaler is appropriate.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a certified check source that has the same isotope as the sealed source. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie for beta or gamma emitters or 0.001 microcurie for alpha emitters, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source. Wipes of alpha emitting radionuclides should be dry and the exposed, single layer of the wipe material should face the detector.

4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcurie or greater for beta or gamma emitting radionuclides or 0.001 microcurie for alpha emitting radionuclides, notify the RSO. The source must be withdrawn from use to be repaired or disposed in accordance with IDPH rules.
7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain records for five (5) years.

APPENDIX H

MODEL RULES FOR SAFE HANDLING OF RADIOACTIVE MATERIALS

In addition to 641-40.61

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix H to IDPH Regulatory Guide Broadscope Regulatory Guide."

If you prefer, you may develop your own rules for safe handling of radioactive materials for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Iowa Rules. Say on your application, "We have developed rules for the safe handling of radioactive materials for your review that are appended as Appendix H," and submit your model rules.

MODEL RULES

1. Protective clothing is to be worn at all times during the preparation, assay, and injection of radiopharmaceuticals. Wear long-sleeved laboratory coats, long pants, and closed toe and heel shoes in all areas where radioactive materials are being used. The protective clothing concept is for at least one protective layer over your skin in the event of a spill.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radioactive material.
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
8. Wear a finger exposure monitor during the preparation and injection of radioactive materials; and at all other appropriate times.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe-test byproduct material use areas and areas where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
12. With a radiation survey meter, survey areas for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled.
14. Always keep syringes, waste, and other radioactive material in shielded containers.

APPENDIX I

MODEL SPILL PROCEDURES

In addition to 641-40.61(4)

You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the model spill procedure published in Appendix I to IDPH Regulatory Guide Broadscope Regulatory Guide."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that is appended as Appendix I" and submit your spill procedures.

MODEL PROCEDURES

MINOR SPILLS OF LIQUIDS AND SOLIDS

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent material.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the authorized user.
6. The authorized user will follow up on the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

MAJOR SPILLS OF LIQUIDS AND SOLIDS

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the authorized user and the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing. Flush contaminated skin with lukewarm water. Wash affected areas with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the "Radioactive Spill Contamination Survey."

MAJOR SPILLS AND MINOR SPILLS

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

Table 1, which may be used as generally guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparison of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values), 51 CFR 1092.

2. "Gamma Radiation Levels for One Curie of Some Radionuclides, "Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.

3. National Council on Radiation Protection and Measurements. "Safe handling of Radioactive Materials," NCRP Report No. 30, paragraph 2.3 and Table 2, 1964.

4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 CFR 29712, Table 1, June 3, 1981.

Table 1 may need to be modified before being used for guidance in a specific area of use.

TABLE I

RELATIVE HAZARDS OF COMMON RADIONUCLIDES

ESTIMATE THE AMOUNT OF RADIOACTIVITY SPILLED. INITIATE A MAJOR SPILL PROCEDURE BASED ON THE FOLLOWING DIVIDING LINE. SPILLS ABOVE THESE MILLICURIE AMOUNTS ARE CONSIDERED MAJOR, BELOW ARE CONSIDERED MINOR.

RADIONUCLIDE	MILLICURIES
I-125, I-131, Co-60	1
P-32, Co-58, Fe-59, Se-75, Sr-85, In-111, I-123, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99m, Tl-201	100

APPENDIX J

MODEL PROCEDURE FOR AREA SURVEYS

in addition to 641-40.27

You may use the following procedure to perform area surveys. If you follow this procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix K to IDPH LAB 1-97 Regulatory Guide."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 641-40.27. Say on your application, "We have developed survey procedures for your review that are appended as Appendix K" and submit your survey procedures.

Describe the type and frequency of radiation surveys that will be conducted in radioactive material use and storage areas and in adjacent unrestricted areas. Explain which surveys are the responsibility of the authorized user and which will be performed as part of your radiation safety audit program. Characterize laboratories and facilities according to the radiological hazard and indicate the types and frequencies of monitoring and surveys performed by designated staff.

MODEL PROCEDURE

TRAINING

Before allowing an individual to perform surveys, the RSO will ensure that he or she has sufficient training and experience to perform surveys independently.

Academic training may be a lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic using and measuring radioactivity
- Biological effects of radiation

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

FACILITIES AND EQUIPMENT

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cesium-137, Cobalt-60).

- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

AMBIENT RADIATION LEVEL SURVEYS

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 2.5 mrem/hr (0.025 mSv) or more (5 rem/year divided by 2,000 hr/year).

- 641-40.26(136C) requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year and the dose in any unrestricted area from external sources does not exceed 2 mrem (0.02 mSv) in any one hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. While the regulations do not specify a specific survey frequency, the licensee is required to ensure that the dose rate limits are not exceeded.

CONTAMINATION SURVEYS

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment

- After any spill or contamination event

- When procedures or processes have changed

- To evaluate the potential contamination of users and the immediate work area, at the end of the day or prior to leaving the area of use, when licensed material is used

- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly

- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

CONTAMINATION SURVEY FREQUENCY

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in Appendix B of Chapter 40, then documented surveys should be performed at least daily.

Table I contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material it has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

TABLE I - SUGGESTED CONTAMINATION SURVEY FREQUENCY			
	< 0.1 ALI	> 0.1 ALI < 1.0	> 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

CONTAMINATION IN UNRESTRICTED AREAS

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table II.

TABLE II - ACCEPTABLE SURFACE CONTAMINATION LEVELS FOR EQUIPMENT			
Nuclide[a]	Average[b,c]	Maximum[b,d]	Removable[b,c]
I-125, I-129	1.7 Bq*/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300 dpm/100 cm^2)	0.3 Bq/100 cm^2 (20 dpm/100 cm^2)
I-126, 1-131, I-133, Sr-90	16.7 Bq/100 cm^2 (1,000 dp/100 cm^2)	50.0 Bq/100 cm^2 (3,000 dpm/100 cm^2)	3.3 Bq/100 cm^2 (200 dpm/100 cm^2)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq*/100 cm^2 (5,000 dpm/100 cm^2)	250 Bq/100 cm^2 (15,000 dpm/100 cm^2)	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)

[a] Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

[b] As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[c] Measurements of average contaminant should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each such object.

[d] The maximum contamination level applies to an area of not more than 100 cm^2.

[e] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

1 Bq = 1 Disintegration per second

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, Table II provides the maximum acceptable residual levels for equipment and Table III provides screening values for building surface contamination. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination

before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 is acceptable to indicate levels of removable contamination.

TABLE III - SCREENING VALUES FOR BUILDING SURFACE CONTAMINATION		
Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm^2)
Hydrogen-3	H-3	$1.2x10^8$
Carbon-14	C-14	$3.7x10^6$
Sodium-22	Na-22	$9.5x10^3$
Sulfur-35	S-35	$1.3x10^7$
Chlorine-36	Cl-36	$5.0x10^5$
Manganese-54	Mn-54	$3.2x10^4$
Iron-55	Fe-55	$4.5x10^6$
Cobalt-60	Co-60	$7.1x10^3$
Nickel-63	Ni-63	$1.8x10^6$
Strontium-90	Sr-90	$8.7x10^3$
Technetium-99	Tc-99	$1.3x10^6$
Iodine-129	I-129	$3.5x10^4$
Cesium-137	Cs-137	$2.8x10^4$
Iridium-192	Ir-192	$7.4x10^4$

Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using the NRC's D and D Version 1.

Table III does not include screening values for radionuclides that emit alpha particles, or for soil contamination. Licensees are encouraged to use site-specific dose assessment based on actual site physical and environmental conditions.

Units are disintegrations per minute per 100 square centimeters (dpm/100 cm^2). 1 dpm is equivalent to 0.0167 Becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 25 mrem/yr. (0.25 mSv/yr.) unrestricted release dose limit in 641-40.29(136C). For radionuclides in a mixture, the "sum of fractions" rule applies.

Table III was derived using the NRC's D and D screening code, Version 1, and its default input parameters. Table III provides criteria that permit licensees to demonstrate compliance with the unrestricted release dose criterion in the License Termination Rule. The values correspond to screening "derived concentration guidelines" for each specific radionuclide based on the methodology. Sites with building surface contamination levels below those listed in Table III would be deemed acceptable for release for unrestricted use in accordance with the dose criteria, provided that residual radioactivity has been reduced to ALARA levels. The table is intended for use as criteria to facilitate license termination for many simple routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in Table III, additional site-specific dose assessments may be necessary.

SURVEY RECORD REQUIREMENTS

Each survey record should include the following:

- A diagram of the area surveyed
- A list of items and equipment surveyed
- Specific locations on the survey diagram where wipe test was taken
- Ambient radiation levels with appropriate units
- Contamination levels with appropriate units
- Make and model number of instruments used
- Background levels
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

APPENDIX K

SAFETY EVALUATIONS OF PROPOSED USES/USERS

641-39.4(28)"b" and "c" require that Type A and B broadscope license applicants establish procedures to assure completion of safety evaluations of proposed uses of byproduct material. The procedures should take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures. The review and approval must be documented by the RSC prior to use of the byproduct material.

Your application should contain the criteria to be used by each committee member when evaluating qualifications of users, facility and equipment adequacy and determining personnel monitoring and survey requirements. IDPH staff recommends that criteria for committee members be maintained in manual form.

The RSC must the review of users and uses of radioactive materials. Therefore, your application must provide enough detail to assure the IDPH staff that the RSC evaluations are sufficient in scope and depth to satisfy 641.39.4(28)"b"(3)"3" and 39.4(28)"c"(2)"2". A copy of proposed user request and RSC approval forms or permits should be submitted for review with your application.

Broadscope licenses involving a wide range of uses should consider the development of a classification scheme of radionuclides according to relative toxicity per unit activity. This classification scheme can be used to correlate standards of design for laboratories based upon toxicity and levels of activity used. The development of your classification scheme should be based upon the types and uses anticipated at your institution. Once a classification scheme has been developed, other required safety functions can be developed and incorporated into the criteria used by the individual committee members when reviewing applications. These should include bioassays and their frequencies, direct and removable contamination surveys, air sampling-provisions, and personnel monitoring. The submission of a classification scheme and criteria is intended to demonstrate to the IDPH staff the minimum standards that will be applied when approving uses.

It is understood that certain permits issued by the RSC may deviate from the classification scheme due to unusual circumstances. However, it is expected that broadscope licensees will adhere to the classification scheme closely and when deviations occur, that justification and documentation of the deviation will be maintained for review by IDPH inspection staff. Your safety evaluation procedures and criteria should include and describe how your RSC will evaluate and apply requirements for the following:

a. The proposed use of material considering the quantity and form requested, potential radiological hazards associated with such use and mechanisms for external and internal exposure control, contamination controls and waste disposal.

b. Training and experience for authorized users and individuals working under the supervision of an authorized user (e.g., technicians). Specialized training for certain users should also be included, e.g., incinerator operators, waste compaction and animal handlers.

c. Facilities and equipment for each specific use.

d. Material handling and operating procedures including provisions for radiation surveys conducted by users to insure that radioactive material does not present a radiation hazard. The type and frequency of surveys must take into consideration the amount and types of radioactive material used or being stored.

The licensee procedures and criteria should be adequate to determine that individual users are qualified to use materials safely and that the facilities are appropriate and adequate. Broadscope licensees are expected to provide detailed review criteria, which they will use to evaluate "in-house" requests. Since these type

licensees have assumed the role and responsibility of the IDPH licensing staff, it is essential that we have assurances that the criteria are at least equivalent in scope and philosophy to that of the IDPH. In addition, it is believed that by obtaining a better understanding of the applicant's review processes, that the numerous conflicts encountered during inspection and subsequent enforcement proceedings will be reduced.

APPENDIX L

ADMINISTRATIVE PROCEDURES

641-39.4(28)"b" and "c" require the establishment of appropriate administrative procedures to assure control of procurement and use of byproduct material; as well as completion of safety evaluations of proposed uses/users of byproduct material.

The administrative procedures should take into consideration such matters as the adequacy of facilities and equipment; training and experience of the user; and operating or handling procedures. The IDPH recommends development of radiation safety manuals as an important vehicle for informing your staff of safety criteria and good health physics practices, IDPH regulations and license commitments. Submission of such manuals is useful in the review of your program.

1. Control of Procurement and Use

Your application should describe the administrative procedures you have established to ensure that all procurement, use, and users of radioactive material are properly authorized by the license and approved by the RSC. The IDPH recommends a procedure that centralizes all purchases or other procurement through an authorized purchasing agent in order to verify that the procurement and use are authorized under the license. If you do not use such centralized procedures, describe how your procedure prevents unauthorized procurement and use.

2. Safety Evaluations of Proposed Uses/Users

Appendix K describes the requirements for this important aspect of a broadscope license program.

3. Emergency Procedures

Your application should describe the program in place for handling spills, fires, releases or loss of material, and accidental contamination of personnel. You should discuss provisions of immediate response and handling of such incidents including off-hours notification of your staff, state and local authorities and the IDPH, when applicable. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, your staff should clearly understand whom they should contact. They must also know that only qualified and experienced individuals should conduct decontamination and recovery operations.

A copy of procedures should be posted in all restricted areas and address, at a minimum, the following:

a. Initial response actions and responsibilities including immediate safety precautions for people and property.

b. Area and facility access control and security.

c. Internal and external notification mechanisms and responsibilities.

d. Provisions for medical and off-site agency assistance.

Consider the strategic placement of emergency spill kits at specified locations throughout your institution for use by authorized users and the radiation safety staff. These kits should be periodically inspected and replenished as necessary.

Consider the establishment of an Emergency Response Team comprised of individuals experienced in various emergency response functions (e.g., radiological, medical, managerial, security and fire protection).

4. Operating and Handling Procedures

Your application should include laboratory operating and handling procedures that describe radiation safety instructions necessary to ensure adequate external and internal exposure controls including contamination controls. You should include the waste disposal practices, personnel and area monitoring criteria, use of protective clothing and equipment, and prohibitions for specific unsafe practices, etc.

5. Other Procedures

Your application should include other administrative procedures as deemed necessary to guide, control and ensure consistency in the implementation of the radiation protection program. You should consider, for example, standard operating procedures (SOPS) for routine health physics activities, including those conducted by the RSOS (e.g., radiation and contamination survey methods, smear analysis, source leak testing, air sampling, etc.).

APPENDIX M

AUDITS AND APPRAISALS

641-39.4(28)"b" and "c" require applicants to establish administrative controls and provisions relating to management review necessary to assure safe operations. Program reviews and/or audits should be conducted by management representatives or independent auditors, the RSC, and the RSO.

1. Management and Radiation Safety Committee Audits

You should discuss senior management oversight and mechanisms used by senior management to ensure that they are aware of IDPH regulations, the provisions of the license, and compliance status of the institution's licensed program. This may include independent audits of the program, frequent meetings with the RSC and periodic tours of selected facility areas.

The RSC should be fully aware of the operations and activities of the Radiation Safety Office through frequent and routine meetings. The RSC should conduct periodic interactive management audits and performance evaluations of the Radiation Safety Office (including the RSO's performance). Results of the RSC's audit and program reviews should be reported to senior management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with IDPH regulations and license conditions. You should also consider establishment of RSC subcommittees to evaluate and audit those areas of the program within their area of expertise.

2. Radiation Safety Officer and Staff Audits

You should describe the audit mechanism implemented by the RSO and the RSO's staff to determine user compliance with the terms and conditions of the IDPH license, RSC approved permits and for adherence to good health physics practices. Your audit program should include routine unannounced inspections of each authorized user's laboratory and practices to supplement and audit the routine monitoring performed by authorized users. Laboratory inspections include the following:

a. Review of user inventory and survey records.

b. Evaluation of user and technician training through discussion and observation of work practices.

c. Performance of independent surveys of user work areas.

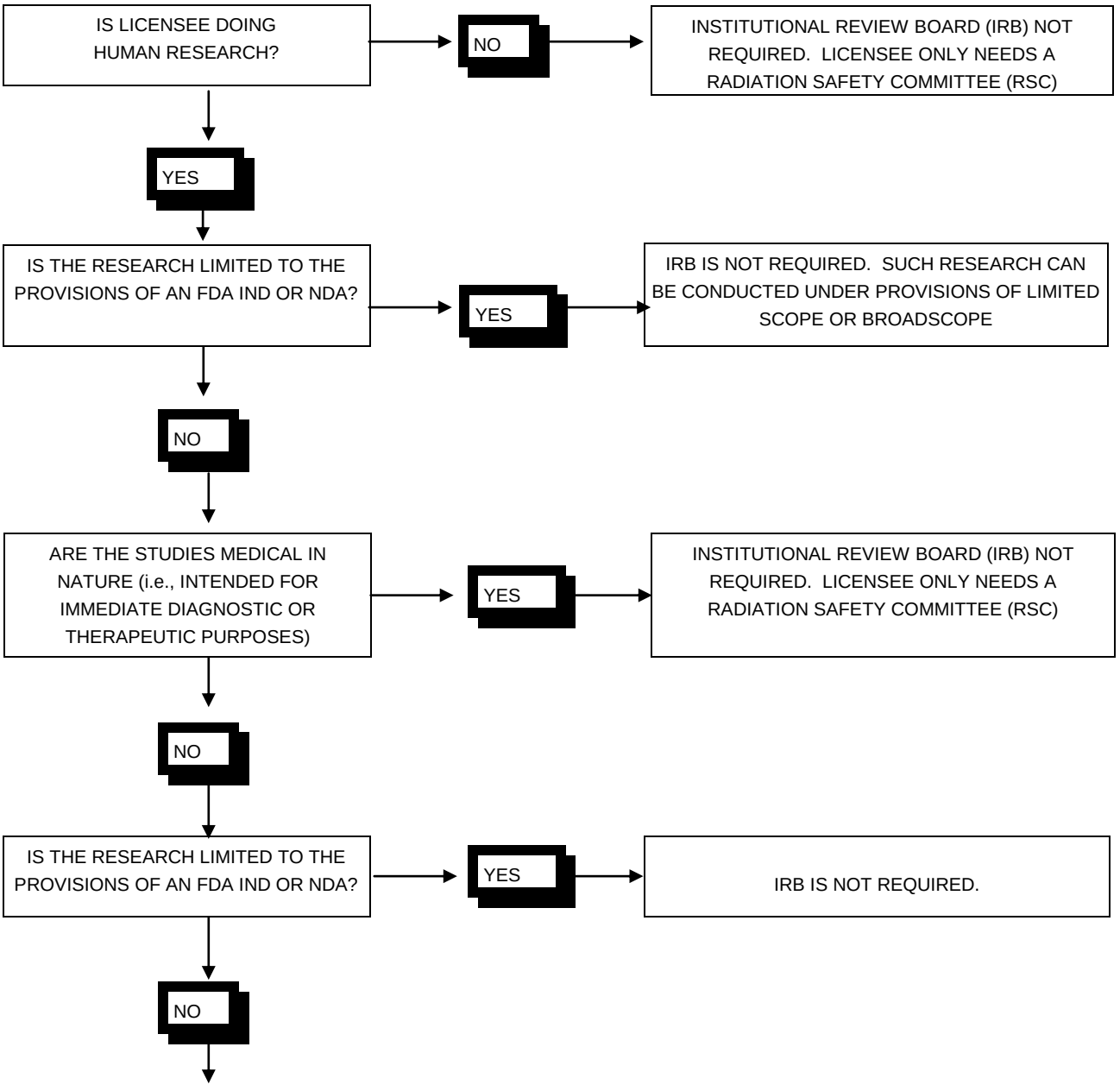
d. Evaluation of compliance with RSC permit and safety manual requirements.

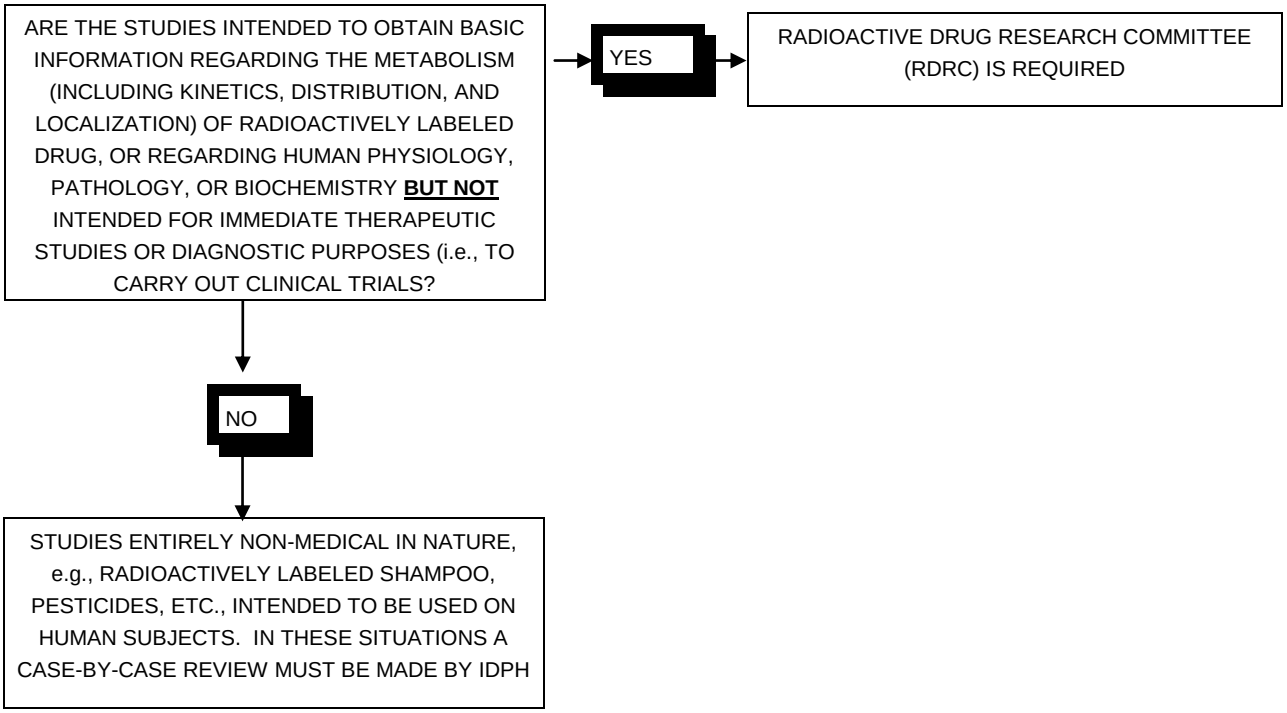
e. Provision for performance based instruction to users and technical level staff.

You should indicate the types and frequencies of monitoring performed. The intervals of surveys and audits should be frequent enough to assure close communications and proper surveillance of individual radioactive material users. For a Type A broadscope license, the surveys and audits are typically performed at least quarterly. However, schedules of surveys and audits may be proposed based upon activity and use (e.g., high level laboratories (weekly), intermediate laboratories, (monthly), and low-level laboratories, (quarterly).

APPENDIX N

FLOW DIAGRAM TO AID IN DETERMINING LICENSEE'S COMMITTEE MEMBERSHIP NEED RELATING TO HUMAN RESEARCH




ARE THE STUDIES INTENDED TO OBTAIN BASIC INFORMATION REGARDING THE METABOLISM (INCLUDING KINETICS, DISTRIBUTION, AND LOCALIZATION) OF RADIOACTIVELY LABELED DRUG, OR REGARDING HUMAN PHYSIOLOGY, PATHOLOGY, OR BIOCHEMISTRY BUT NOT INTENDED FOR IMMEDIATE THERAPEUTIC STUDIES OR DIAGNOSTIC PURPOSES (i.e., TO CARRY OUT CLINICAL TRIALS?
YES
RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC) IS REQUIRED
NO
STUDIES ENTIRELY NON-MEDICAL IN NATURE, e.g., RADIOACTIVELY LABELED SHAMPOO, PESTICIDES, ETC., INTENDED TO BE USED ON HUMAN SUBJECTS. IN THESE SITUATIONS A CASE-BY-CASE REVIEW MUST BE MADE BY IDPH

APPENDIX O

MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

In addition to 641-40.65

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix O to IDPH Broadscope Regulatory Guide."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 641-40.65. Say on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix I," and submit your procedure.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials. That individual must ensure that the user is authorized the requested materials and quantities and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

    a. For routinely used materials

        (1) Written records identifying the authorized user or department, isotope, chemical form, activity, and supplier will be made.
        (2) A check to confirm that material received was ordered through proper channels.

    b. For occasionally used materials

        (1) The authorized user who will use the material will make a written request to confirm that the material received is what was ordered.
        (2) The person who receives the material will check the written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.

4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum.

SAMPLE MEMORANDUM

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrives during other than normal working hours. Packages should be placed on a cart and taken immediately to the Radioactive Materials Department, Room _____. Unlock the door, place the package on top of the counter, and re-lock the door.

If the package appears damaged or leaking, you should immediately contact one of the individuals identified below. Ask the carrier to remain until it can be determined that the driver and the delivery vehicle are not contaminated.

If you have any questions concerning this memorandum, please call our Radiation Safety Officer.

_____ _____

Name Home Telephone

APPENDIX P

FINANCIAL ASSURANCE, RECORDKEEPING, DECOMMISSIONING AND EMERGENCY PLANS

1. Financial Assurance and Recordkeeping Requirements

The IDPH has established technical and financial regulations for decommissioning of licensed facilities. The regulations address the decommissioning planning needs, timing, funding methods, and environmental review requirements for public and private facilities holding licenses, with the exception of uranium mills. The intent of the regulations is to ensure that the decommissioning of all licensed facilities-will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. The financial assurance requirements of the rule are addressed in 641-39.4(26).

2. Decommissioning Plan Requirements

641-39.4(26) requires certain licensees to submit, on or before the license expiration date, a plan for completion of decommissioning when the licensee decides to terminate the license. In particular, those sections require a licensee to submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously approved by the IDPH.

In addition to broadscope license materials programs, panoramic irradiators and large-scale well-logging operations licensed under 641 Chapter 39 may require submission of a decommissioning plan. Based upon the above, in order to facilitate the release of your facilities for unrestricted use, you should consider incorporating plans for decommissioning facilities into your application. If you are required to provide financial certification, then the submission of a decommissioning plan should be part of your application.

Most applications for routine R&D activities contain procedures for cleanup activities related to routine processing and handling of spills. These procedures are normally sufficient and obviate the need for a formal decommissioning plan.

Should release criteria be submitted in an application and deemed adequate, these criteria can be tied into the license and thereby authorization granted to the licensee for release of facilities/equipment. This process reduces the number of individual amendments dealing with routine release of use areas. To use this provision, license applications must incorporate information regarding closeout survey release criteria to be followed and records to be retained regarding released areas. The release criteria should coincide with decontamination limits and include the following:

a. description of the survey record to be retained.

b. person performing the survey.

c. instrumentation used.

d. release criteria.

e. commitment to maintain the records relevant to decommissioning.

3. RADIOLOGICAL EMERGENCY PLANS

641-39.4(24)"g"(1) requires applicants that request possession of radioactive materials in both unsealed and certain sealed forms in excess of specifically listed quantities, address the need for an Emergency Plan.

Should your assessment support the need for an emergency plan, the plan must be submitted with your application. Most byproduct material licensees, except those who need multi-curie amounts of Iodine-131,

Iodine-125, or certain other nuclides in unsealed forms can maintain their possession limits below those requiring an emergency plan as specified in 641 Chapter 39 Appendix G. If the sum of the nuclide ratios exceeds the threshold for emergency planning and it appears that the quantities could be reduced below that threshold, you should consider options to reduce the requested possession limits below the threshold. If you do not choose to reduce the possession limit below the threshold, you must either submit an evaluation demonstrating that an emergency plan is unnecessary or submit an emergency plan. Refer to 641-39.4(24)"g"(1)"1" and 641-39.4(24)"g"(2) for the applicable requirements.

APPENDIX Q

INFORMATION REQUIRED FOR FIELD USE OF BYPRODUCT MATERIAL

10 CFR 51.22(c)(14)(v) identifies certain categorical exclusions for environmental assessments that includes an exclusion for radioactive material for research and development, and for educational purposes. However, this categorical exclusion does not encompass performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study, (e.g. tagging of animals or insects that remain in the wild). These type requests may require an environmental assessment. Field studies that do not deliberately release radioactive material into the environment, such as tagging of animals and penning them to prevent escape, may be eligible for a categorical exclusion.

The use of byproduct material in field uses will be considered if the licensee provides the following:

1. A complete application describing the type and amount of material to be used, the location of use, and training and experience of the individuals who will be using the material.

2. A complete experimental protocol.

3. A description of the amount of radioactive material to be released in the field; decontamination procedures at the conclusion of the experiment (if appropriate); and procedures for minimizing releases.

4. A description of the expected radiation dose to humans.

5. The written permission from the property owner to use radioactive materials at the proposed site.

6. A letter from the Department of Natural Resources (DNR) and any other appropriate regulatory authority indicating that they have reviewed your application and concur with your request.

APPENDIX R

RADIOACTIVE MATERIALS USED IN ANIMALS

If radioactive materials will be used in animals, submit the following:

1. Specification of the facilities to be used to house the animals.
2. Instructions to be provided to animal caretakers for handling animals, animal wastes, and carcasses.
3. Instructions for cleaning and decontaminating animal cages.
4. Procedures for securing animal rooms when unattended by authorized users.

The following information is provided to assist you in responding to the above. You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the model spill procedure published in Appendix R to IDPH Regulatory Guide."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed procedures for your review that are appended as Appendix R" and submit your procedures.

A. RADIATION SAFETY PROCEDURES FOR THE CARE AND HANDLING OF ANIMALS ADMINISTERED RADIOACTIVE MATERIAL

1. Only individuals approved by the RSC (Type A Broadscope license) or RSO (Type B and Type C Broadscope license) shall be involved in the care and handling of animals that have been administered radioactive materials.

2. The door(s) to animal housing areas shall be locked at all times when animals are present. Only authorized personnel trained in radiation safety shall have access to these areas.

3. The door(s) to animal housing areas, and each cage containing a radioactive animal, shall be conspicuously posted with a "Caution Radioactive Material" sign.

4. Authorized personnel must record the appropriate information and sign the log near the door each time they enter or leave the animal housing area.

5. Personnel providing care to animals shall wear lab coats, disposable gloves (and boots, if appropriate), and whole body dosimeters (extremity dosimeters may also be required).

6. Disposable gloves and boots shall be removed at the entrance and placed in a radioactive waste container before leaving the housing area. Hands, feet, and clothing shall be checked for contamination at this time using a portable survey meter.

7. Animals shall be fed and watered using disposable dishes that will be placed, after use, in the radioactive waste container.

8. Animal excreta shall be collected daily, sealed in plastic bags, properly labeled, and frozen (if necessary). Excreta may not be disposed of as normal waste until the radiation levels from it have reached background.

9. Adequate precautions must be employed for the transfer of treated animals through unrestricted areas to prevent contamination of these areas by excreta.

10. In case of animal death, the carcass must be frozen and stored as radioactive waste until its radiation levels have reached background.

11. A radioactive contamination survey of the housing area shall be performed each day during which an animal is housed.

12. The animal housing area shall not be used for other purposes until surveys indicate that it is free of contamination.

B. RELEASE CRITERIA FOR ANIMALS DIAGNOSED OR TREATED WITH RADIOACTIVE MATERIAL

In accordance with the recommendations of NCRP Report No. 91 and the requirements of 641 Chapter 40, the total effective dose equivalent to any member of the general public from the diagnostic or therapeutic use of radioactive materials in animals shall be maintained "as low as reasonably achievable" (ALARA). In all cases, this should be less than 100 mrem. The total effective dose equivalent to any member of the public who is pregnant or under the age of 18 shall be maintained below 20 mrem. Toward these ends, the following criteria for release of animals administered radioactive material shall be established:

1. ANIMALS ADMINISTERED TECHNETIUM-99m

   a. Any small animal considered a pet that has been diagnosed using Technetium-99m shall not be released to its owner or any other member of the general public until radiation levels have reached natural background. The radiation levels shall be measured at the surface of the animal with an appropriate portable survey instrument. This will generally require that the animal be held for 24 to 48 hours after injection.

   b. Any small animal not considered a pet or any large animal that has been diagnosed using Technetium-99m should not be released to its owner or any other member of the public until radiation levels have reached natural background. The radiation levels shall be measured at the surface of the animal with an appropriate portable survey instrument. However, at the discretion of the attending veterinarian, the animal may be released provided the levels are below 2 mR/hr at the animal's surface. This will generally require that the animal be held for at least 24 hours after the time of injection.

2. ANIMALS ADMINISTERED IODINE-131

   Any animal that has been treated with Iodine-131 shall not be released to its owner or any other member of the public until
   - Maximum exposure rate of 5.0 mR/hour at 1 foot from the patient
   - Three – day minimum stay post injection and
   - Owner advised not to sleep with the patient for seven days post release.

C. WRITTEN INSTRUCTIONS FOR OWNERS OF ANIMALS TREATED WITH IODINE-131

The following information is provided to assist you in responding to the above. You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the procedure published in Appendix R to IDPH Regulatory Guide for the written instruction for owners of animals treated with Iodine-131"

If you prefer, you may develop your own procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed procedures for your review that are appended as Appendix R" and submit your procedures.

Care of Animal Injected with Iodine-131

Your pet has been treated with radioactive iodine (I-131), and will continue to excrete small amounts of radioactive iodine in fluids and feces for some time. The present level of your pet's radioactivity is below that which our state regulatory agency requires for complete isolation of your animal. However, because some radioactivity will be excreted from your pet for the next few weeks, it is required that you agree to the following precautions:

Injection Date & Time: _____

Released by:_____ _____ _____
(Authorized User) Date Time

For the **first two weeks** following release:

- Minimize close contact with your pet.
- **Do NOT sleep with your pet.**
- Do not allow children or pregnant women to have **any contact** with your pet.
- Maintain your pet's litter pan in an isolated area.
- Wear disposable latex or rubber gloves while handling your pet or its litter.
- Collect litter daily, place in a plastic bag and dispose of all materials (including gloves) in the receptacle provided. Maintain this receptacle in an outside location and hold all contents for six weeks prior to final disposal of both receptacle and contents.

Between **2 and 6 weeks** following release:

- Minimize close contact with your pet.
- Do not allow children or pregnant women to have **any contact** with your pet.
- Wear disposable latex or rubber gloves while handling your pet or its litter.
- Collect litter daily, place in a plastic bag and dispose of all materials (including gloves) in an outside receptacle. These materials should now be collected separately from the initial two weeks of litter, at the end of six weeks no additional holding time is required.

Six weeks following release:

- Close contact with your pet is allowed and animal waste may be treated as regular waste.

If you have any questions concerning these requirements, please contact:

I have read and understand these requirements. I acknowledge that it is my responsibility to minimize the radiation exposure to others and myself by following these guidelines.

_____ _____ _____
Signed **Date** **Time**

APPENDIX S

INCINERATION GUIDELINES FOR MATERIAL LICENSEES

These guidelines apply to non-commercial waste disposal, i.e., incineration of a licensee's own waste. IDPH may request additional information regarding proposed commercial incinerators as appropriate to assess the potential impact on public health and safety and the environment.

You do not need specific IDPH approval in order to incinerate certain categories of radioactive waste. For example, 641-40.74(1)"b" provides that tritium and Carbon-14 in low concentrations (less than or equal to 0.05 microcuries per gram of animal tissue) in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After you have reviewed your program and confirmed that you have waste that requires specific IDPH approval for incineration, please provide all of the information specified below:

1. State specifically the isotopes and the maximum activity of each isotope that you wish to incinerate per burn. Indicate the form of the waste (e.g., paper, bedding, animal carcasses).

2. State the maximum number of burns to be performed in any one-week and the maximum number of burns per year. Describe your procedures for assuring that these frequencies and activities will not be exceeded.

3. Describe the characteristics of the incinerator and site, including:
   (a) Height of stack,
   (b) Rated airflow (cubic feet per hour, or similar units),
   (c) Proximity of the stack or other discharge to occupied areas, (e.g., residences, school, or hospital),
   (d) Distance to the nearest air intake ducts of adjacent buildings,
   (e) The scrubbers, filters, or air cleaning equipment installed.

4. State how you will determine the concentration of radionuclides released, both as airborne effluent, and as any liquid effluent from scrubbers, condensers, or associated systems. Describe any stack monitoring, which is planned.

5. Submit calculations demonstrating that concentrations of radioactive material in the effluent air at the stack or unrestricted area will be in accordance with the requirements or 641-40.27(3).

6. In order to comply with the As Low As Reasonably Achievable (ALARA) philosophy stated in 641-40.10(2) the gaseous effluent from the incinerator stack should:
   (1) not exceed the limits specified for air in Appendix B, Table II, 641-Chapter 40, when averaged over a twenty-four hour period, and
   (2) be a fraction (approximately 10 percent) of the limits specified for air in Appendix B, Table II, 641-Chapter 40, when averaged over one year.

   Describe how your proposed activities will meet these criteria or describe why they are not reasonably achievable.

7. Describe the method of measurement or estimation of the concentration of radioactive material appearing in ash residue. Include the minimum detectable activity (MDA), which can be measured. Unless you present scientific evidence to the contrary, you must use the most conservative assumption.

8. Describe the procedures for handling, storing, and disposing of ash from the incinerator. If you wish to dispose of the ash as normal waste, except for ash containing only radioactive material with a physical half-life of less than 65 days, include the information specified in 641-40.71(136C).

9. If ash is going to be disposed in a landfill, describe what assurances that multiple sources sent to a landfill will not create a health and safety or environmental problem.

10. For radioactive materials with a physical half-life of less than 65 days, describe the procedures for monitoring the ash to determine that the radioactivity in the ash cannot be distinguished from background. Describe the type of radiation detection instrumentation, instrument sensitivity, and sampling and surveying techniques that will be used to determine that the radioactivity in the ash cannot be distinguished from background.

11. Describe procedures to prevent-or limit exposure of personnel to radiation and/or radioactive material during all phases of the operation, including instruction given to personnel handling the combustibles and the ash.

12. Obtain other federal, state and local incineration permits, as applicable. Compliance with IDPH regulations does not relieve the licensee from other Federal, State, and local regulations concerning incineration of radioactive material, operation of the incinerator, or the disposal of the ash. Submit evidence that all regulations concerning incineration of radioactive material, operation of the incinerator, or disposal of the ash have been met or are in the process of being met.

APPENDIX T

MODEL PROCEDURE FOR WASTE DISPOSAL

In addition to 641-40.88

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that was published in Appendix T to IDPH BSREG 98 Regulatory Guide."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of 641-40.70. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as Appendix T" and attach your procedure.

OVERVIEW

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. Nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See 641-38.4(1) and 40.88))

GENERAL GUIDANCE

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, and pathogenicity), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 641-40.72. There are specific limits based on the total sanitary sewerage release of your facility. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to Chapter 641-40. These limits normally apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (641-40.74). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date it was sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Before disposal as in-house waste, monitor each container as follows:
   a. Check your radiation detection survey meter for proper operation.
   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
   c. Remove any shielding from around the container.
   d. Monitor all surfaces of each individual container.
   e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be sure that no radiation labels are visible.
   f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, and then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed following 641-39.4(22)"i" is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

APPENDIX W

DEFINITIONS AND ACRONYMS

As used in this Standard Review Plan:

1. Authorized User: An individual specifically named and authorized by the Radiation Safety Committee to use licensed material without supervision.

2. Certifying Official: An individual authorized and empowered by an institution's management to sign official license documents and correspondence.

3. Institutional Review Board (IRB): A Food and Drug Administration (FDA) approved committee responsible for evaluating risk and benefit of human use medical research proposals.

4. Laboratory Classification Scheme: A system of evaluating and assigning a ranking to a laboratory or facility, based on its suitability as a radioactive material use area.

5. Laboratory Technician: An individual whose normal duties involve laboratory research related work with radioactive materials under the supervision of an authorized user.

6. Radiation Worker: Any individual whose duties require work with radioactive material.

7. Radioactive Drug Research Committee (RDRC): A Food and Drug Administration (FDA) approved committee responsible for evaluating and approving proposals for radioactive drug research in human subjects.

8. Radiation Safety Committee (RSC): A committee responsible for development and administration of an institution's licensed broadscope radioactive material program including responsibility for approval of all proposals for radionuclide use and users.

9. Radiation Safety Officer (RSO): An individual responsible for day-to-day operation of a radiation protection program within an institution.

10. Radiation Safety Office Staff (RSOS): A technical support staff responsible for day-to-day operation of a radiation protection program within an institution, as directed by an RSO.

REVISION	SECTION	DESCRIPTION
12/26/00	ALL	Reformat text. Changed address for Bureau of Radiological Health
04/13/01	Appendix F	Revised and expanded section on bioassays
04/13/01	Appendix J	Revised entire appendix
04/13/01	All	Re-designated as BSREG-01
10/02/01	Item 11.1	Added discussion concerning the Radiation Safety Officer. Renumbered subparagraphs in this section.
01/18/01	Section 7	Added information concerning inspections.
03/13/03	Section 1.4	Changed web address for IDPH rules and publications.
12/07/04	Appendix H	Added requirement for long-sleeve laboratory coats.
07/01/05	ALL	Changed address for Bureau of Radiological Health
01/16/07	Appendix R	Release criteria and precautions for care of animals after release (I-131)
07/17/07	Appendix B	Added new Model Delegation of Authority
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.